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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,150	08/30/2006	Jean-Francois Butty	MEMI-2	6130

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EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
4116	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,150	BUTTY ET AL.	
	Examiner	Art Unit	
	RONALD J. HUPCZEY, JR.	4116	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In response to the Preliminary Amendment filed on August 6th 2006, claims 1-12 have been canceled and the newly added claims 13-24 are pending.

Drawings

2. The drawings are objected to because Figure 1a has been omitted from the included drawings. The figure is included on page 6 of the specification and is needed to fully determine the scope of the subject matter intended to be claimed.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation ""... the respective central and end monopolar electrodes ..."" in the second and third lines of the claim. Examiner notes that the referred to claim 13 only references "... at least two end electrodes arranged towards opposite ends of the catheter .... adapted to function in monopolar mode.". There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 19, the recitation therein of "… a catheter according to claims 13" renders the claim indefinite. As currently written, Examiner is unable to ascertain which specific elements of claim 13 are intended to be included within claim 19. Examiner recommends Applicant in order to overcome the rejection, to include each specific element which Applicant intends the catheter to contain within the body of claim 19.

Claims 20 and 21 are rejected based on their dependency to claim 19.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 13-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1).

Regarding claim 13, Champeau discloses a catheter (catheter **10**) containing at least one pair of bipolar electrodes (electrodes **30**, **32**, **34**, **36**, **38**), each bipolar electrode containing supply channels (apertures **68**) adapted to perfuse saline solution around the electrodes (see col. 8, lns.

4-9). Champeau further discloses the catheter to contain at least two end electrodes (electrodes **30**, **32**, **34**, **36**, **38**) adapted to function in a monopolar manner (see col. 3, lns. 33-35). While Champeau fails to specifically recite the limitation of a pointed tip for piercing insertion, the inclusion of a sharp tip on a catheter is something old and well known in the art which allows for easier insertion of the catheter into the target tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sharp tip on the end of the catheter to allow for easier insertion into the target tissue. The disclosure by Champeau of the structure of the catheter readily allows for such a shape to be created when it is formed and motivation to dispose such.

Regarding claim 14, Champeau discloses a catheter containing bipolar electrodes (electrodes **30**, **32**, **34**, **36**) with at least two saline solution supply channels (lumen **66**).

Regarding claim 15, Champeau discloses liquid supply channels (lumen **66**) with outlets (bores **68**) arranged near the front and rear ends of the catheter and capable of supplying saline solution independently of other outlets contained on the catheter (see col. 8, lns. 4-11).

Regarding claim 16, Champeau discloses a plurality of electrodes (electrodes **30**, **32**, **34**, **36**) disposed on the catheter body, each respective electrode having an individual connecter (microhelical wires **18**, **20**, **22**, **24**, **26**) associated with it and for the electrodes to be capable of applying either bipolar or monopolar energy (see col. 3, lns. 30-34).

Regarding claim 18, Champeau discloses liquid supply channel outlets (bores **68**) spaced a distance from the electrodes (electrodes **30**, **32**, **34**, **36**, see figure 1).

Regarding claim 19, Champeau discloses a catheter (catheter **10**) containing at least one pair of bipolar electrodes (electrodes **30**, **32**, **34**, **36**), each bipolar electrode. Champeau further

discloses the catheter, when containing multiple electrodes on the catheter body, to contain a plurality of lumens allowing for selective fluid delivery to the particular electrode which requires cooling (see col. 8, lns. 4 – 30). While not specifically disclosing two independently controlled pumps, it would have been obvious to one of ordinary skill in the art at the time of the invention that the apparatus disclosed by Champeau would be associated with multiple pumping sources to allow for selective delivery of saline solution as well as individual control of injection rate.

Regarding claim 20, Champeau discloses a temperature acquisition unit (microprocessor-based control system, see col. 8, lns. 24 – 30) connected to the thermocouples within the catheter.

Regarding claim 21, Champeau discloses an RF generator associated with the apparatus. Champeau further discloses a computing unit (microprocessor-based control system) connectable to the temperature acquisition unit, pumps and RF generator functioning to provide control and monitoring of the operations (see col. 8, lns. 24-30).

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) further in view of Houser et al (US Pub. No. 2002/0035361 A1).

Regarding claim 17, Champeau discloses thermocouples disposed within the catheter tip and functioning to measure the temperature of the surrounding tissue. Champeau fails to disclose the thermocouples to be retractably mounted in the catheter. Houser et al discloses a catheter containing a plurality of central bores **(146)** and side bores **(148)** with temperature sensors **(150)** retractably disposed within the bores (see paragraph [0086]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

include the retractable temperature sensors disclosed by Houser et al with the catheter, lumen, bores and temperature sensing circuitry disclosed by Champeau to allow for a catheter with sensing means insertable into the surrounding tissue. Both inventions are directed towards the same field of invention, radiofrequency ablation to tissue, and the disclosed structures of Champeau readily allow for such temperature sensors of Houser et al to be disposed within the catheter. The combination would further provide for a device which can sense temperature increases at depth in the surrounding tissue and allow for greater control of the ablation process.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) further in view of Mulier et al (US Pat. No. 6,537,248 B2).

Regarding claim 22, Champeau discloses a catheter containing a pair of bipolar electrodes (electrodes **30**, **32**, **34**, **36**, **38**, see col. 3, lns. 30-33) with saline supply channels functioning to perfuse saline (apertures **68**, see col. 8, lns. 4-9) and two monopolar electrodes (electrodes **30**, **32**, **34**, **36**, **38**, see col. 33-35) arranged towards opposed ends of the catheter on either side of the bipolar electrodes. Champeau further discloses inserting the catheter into a region of tissue to be ablated (see abstract). Champeau fails to specifically disclose the actuation of the monopolar electrode proceeded by the perfusion of saline and the actuation of the bipolar electrodes. Mulier et al discloses an electrode used in conjunction with a conductive fluid (i.e. saline) functioning to ablate tissue (see abstract). Mulier et al discloses a criticality for providing a tight seal around the puncture site to prevent heated conductive fluid from escaping from the puncture site and to contain the perfused conductive fluid within the desired portion of tissue (see col. 7, lns. 15-26). Therefore, it would have been obvious to one of ordinary skill in the art

at the time the invention was made to supply RF energy to first seal the puncture using the electrodes functioning in a monopolar manner, perfusing a conductive fluid around the bipolar electrode and then supplying RF energy to the bipolar electrodes to provide thermal ablation to the surrounding tissue. The disclosure of Muiler et al readily provides motivation for operating the device disclosed by Champeau in such a manner. The combination allows for the maintaining of the conductive fluid within the treatment area, in turn allowing for more effective application of the RF energy and preventing unwanted areas of tissue from being treated.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) in view of Mulier et al (US Pat. No. 6,537,248 B2) further in view of Ellsberry et al (US Pub. No. 2001/0025176 A1) and "Comparison of monopolar and bipolar electrosurgical modes for restorative dentistry: A review of the literature" by Livaditis (hereinafter as Livaditis).

Regarding claim 23, Champeau discloses perfusing saline via supply channels (apertures **68**) arranged over the catheter. Champeau fails to specifically recite the step of perfusing saline at a lower concentration from the channels proximate the bipolar electrodes than the concentration at the channels proximate the monopolar electrodes. Mulier et al is also silent regarding a concentration differential. Ellsberry et al discloses an electrosurgical device utilizing a conductive fluid to aid in providing a conductive path for RF energy to travel on. Ellsberry et al further discloses that the greater the ionic concentration (i.e. sodium chloride in saline), the more aggressive the rate of ablation (paragraph [0081]). Livaditis discloses the functioning of monopolar and bipolar electrodes when placed within tissue. Livaditis teaches that the bipolar

application of energy results in the tissue located directly between the electrodes in the path of the highest current density (see pg. 394, left column, second paragraph). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide a higher concentration saline solution around the monopolar electrodes of Champeau or Mulier in comparison to the bipolar electrodes as taught by Ellsberry and Livaditis. The combination is readily allowed by the disclosure of multiple, individually controllable fluid supply means by Champeau. Motivation is such that providing such a concentration differential allows for the tissue within the direct current path (i.e. between the bipolar electrodes) to be effected by the same amount of ablative energy as the tissue located towards the monopolar electrodes.

11. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) in view of Mulier et al (US Pat. No. 6,537,248 B2) further Ellsberry et al (US Pub. No. 2001/0025176 A1) and "Comparison of monopolar and bipolar electrosurgical modes for restorative dentistry: A review of the literature" by Livaditis (hereinafter as Livaditis) and furthermore in view of Houser et al (US Pub No. 2002/0053561).

Regarding claim 24, the combination of Champeau, Mulier et al, Ellsberry et al and Livaditis, as set forth in claim 23 above, is all silent in regards to a retractable temperature sensing means. Further, the combination fails to disclose the thermocouples to be retractably mounted in the catheter tip. Champeau, however, discloses thermocouples disposed within the catheter tip and functioning to measure the temperature of the surrounding tissue (see col. 8, lns. 13-30). Houser et al discloses a catheter containing a plurality of central bores **(146)** and side

bores (**148**) with temperature sensors (**150**) retractably disposed within the bores (see paragraph [0081]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of inserting the retractable temperature sensors as taught by Houser et al into the tissue before or during the operation of the bipolar electrodes to allow for an acquisition of temperature data to assess the effects on the surrounding tissue.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Monday through Friday (7:30 A.M. to 5:00 P.M. EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe H. Cheng can be reached on 571-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. H./
Examiner, Art Unit 4116
7/15/08

/Joe H Cheng/
Supervisory Patent Examiner
Art Unit 4116